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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,104	08/10/2000	Xiaobo Wang	47184-20001.00	6349

25225 7590 10/02/2003

MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER	
STARSIAK, JOHN S	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/636,104	Xiaobo Wang et al.
Examiner	**Group Art Unit**
J. STARSIAK	1753

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on 10 August 2000.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Dispo ition of Claims

☒ Claim(s) 1-69 is/are pending in the application.

Of the above claim(s) 53-67 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-36, 39-49, 68, and 69 is/are rejected.

☒ Claim(s) 37, 38, and 50-52 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certifi d copies not received: _____.

Atta hm nt(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-52, 68, and 69, drawn to a process and kit, respectively, for manipulating a moiety in a microfluidic device, classified in several class/subclasses including class 204, subclass 547 and 643, respectively .

II. Claims 53-61, drawn to a method for isolating an intracellular moiety from a target cell, classified in class 435, subclass 325.

III. Claims 62 and 63, drawn to a method of generating a cDNA library, classified in class 435, subclass 701.

IV. Claims 64-67, drawn to a method of determining gene expression in a target cell, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons: Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case each of the groups constitutes a different invention. The only step the different inventions have in common is the "coupling" step.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search for one group is not required for the remaining groups restriction for examination purposes as indicated is proper.

During a telephone conversation with Peng Chen on 08 September 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-52, 68, and 69. Affirmation of this election must be made by applicant in replying to this Office action. Claims 54-67 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a structure that is external to said chip" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10, 19, 26, 27, 29 and 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 8 recites, wherein the binding partner is selected from the group consisting of a cell, a cellular organelle, a virus, a microparticle, an aggregate or complex of molecules and an aggregate or complex thereof. While there is a recitation which corresponds to this claim in the specification in the written description of the invention, the only binding partner described in any detail is "a microparticle". Claim 19 recites, wherein the physical force is selected from the group consisting of a dielectrophoresis, a traveling-wave dielectrophoresis, a magnetic, an acoustic, an electrostatic, a mechanical, optical radiation, a thermal convection force. Claim 49 contains a

similar recitation. While there is a recitation in the written description of the invention which corresponds to this recitation and outlines of embodiments of the invention base on mechanical force, optical radiation force and thermal convection force, there is no detailed description(including figures) of the embodiments of the invention based upon mechanical force, optical radiation force, or thermal convection force. The remaining claims are rejected because they depend on one of the above claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 30, 31, and 40-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites a "cleavable linker". The meaning of this term is unclear. For example does cleavage occur between the linker and the moiety or does cleavage occur between the linker and the binding partner? Claim 30 recites, "a plurality of microunits". Claim 31 recites " a single unit'. Neither of these terms are defined in the context of the present invention. MPEP 608.01 (o) states: "The meaning of every term used in any of the claim should be apparent from descriptive portion of the specification with clear disclosure to its import; and in mechanical cases, it should be identified in the descriptive portion of the specification by reference to the drawing, designating the part or parts therein to which the term applies.". For example, it is unclear if the traveling dielectrophoresis embodiment of the invention consists of a single unit or plurality of units. Claims

40-45 recite: "wherein the moiety is not directly manipulatable by a dielectrophoretic force", "wherein the moiety is not directly manipulatable by a traveling-wave dielectrophoresis force", "wherein the moiety is not directly manipulatable by a magnetic force", "wherein the moiety is not directly manipulatable by an acoustic force", wherein the moiety is not directly manipulatable by an electrostatic force", and "wherein the moiety is not directly manipulatable by an optical radiation force", respectively. Each of these claims is indefinite because it recites a rationale for the coupling step recited in claim 1. Moreover, if these recitations are indefinite because not specific force is recited in claim 1. In other words, the limitation of claim 40 for example is meaningless unless the physical force is dielectrophoresis. Claims 46 and 47 recite, "wherein the moiety to be manipulated is *substantially coupled* to the binding partner" and "wherein the moiety to be manipulated is *completely coupled* onto surface of the binding partner", respectively. The terms "substantially coupled" and "completely coupled" are relative terms which render the claims indefinite. The terms "substantially coupled" and "completely coupled" are not defined in the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would be reasonably appraised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122 (b), by another in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United states and was published under Article 21(2) of such treaty in the English language.

Claims 1-16, 19-29, 32, 42, and 46-49 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Hughes & Morgan (Anal. Chem., 1999, 71, 3441-3445).

Regarding claim 1, the "coupling step" reads on the "protein coupling" step of Hughes & Morgan. Specifically, Hughes & Morgan teach [page 3442, right hand column]: "Protein coupling was performed as follows: to a solution of EDAC-activated spheres...was added 250 μL of 10mg/mL rabbit anti-goat IgG....". Regarding claim 1, the "manipulating" step reads on the "DEP separation of sphere types" of Hughes & Morgan. Specifically, Hughes & Morgan teach [page 3445, left hand column]: "A mixture of equal quantities of unlabeled and IgG-labeled spheres was resuspended in ultrapure water...and micropipetted onto an electrode array...When an applied potential of peak amplitude 5V at a frequency of 5 MHZ was applied to the electrodes, both types of spheres experienced DEP, but in opposite directions so that spatial separation of the particles was observed. The "structure that is built in said chip" recited in claim 1 reads on the "microelectrodes" of Hughes & Morgan. Specifically, Hughes & Morgan teach [page 3443, left

hand column]: "The electrodes used for crossover frequency measurements and for separation experiments were of the "castellated" design with square dimensions of 10 μm all faces. An SEM of the electrodes is shown in Figure 2.". The "structure that is external to the chip" recited in claim 1 reads on the "signal generator" of Hughes & Morgan. Specifically, Hughes & Morgan recite [page 3443, right hand column]: "Electrodes were powered using a Hewlett-Packard signal generator...". Claim 2 reads on Hughes & Morgan since the "molecule" recited in the Markush group of claim 2 clearly reads on the "rabbit anti-goat IgG" of Hughes & Morgan. Claim 3 further limits the "cell" recited in the Markush group of claim 2. Claim 4 further limits the "cellular organelle" recited in the Markush group of claim 2. However, both of these claims read on Hughes & Morgan because they recite "a molecule". Regarding claim 5, the "organic molecule" recited in the Markush group of claim 5 reads on the "rabbit anti-goat IgG" of Hughes & Morgan. Claim 6 further limits the "an organic molecule" recited in the Markush group of claim 5. This claim reads on Hughes & Morgan since the claim recites "an organic molecule". Regarding claim 7 the "protein" recited in the Markush group of this claim reads on the "rabbit anti-goat IgG" of Hughes & Morgan. Regarding claim 8, the "microparticle" recited in this claim reads on the "EDAC-activated spheres"of Hughes & Morgan. Claim 9 further limits the "cell" recited in the Markush group recited in claim 8. Claim 10 further limits the "cellular organelle" recited in the Markush of claim 8. Both these claims read on Hughes & Morgan because they recite a "protein". The size range of the "microparticles" recited in claim 11 reads on the spheres of Hughes & Morgan. Specifically, Hughes & Morgan teaches [page 3442, right hand column]:

"Carboxylate-modified latex spheres, 216 nm diameter...". 216 nm corresponds to 0.216 microns. Regarding claim 12, the "plastic particle" recited in the Markush group of this claim reads on the "latex spheres" of Hughes & Morgan. Claim 13 reads on Hughes & Morgan because the "rabbit anti-goat IgG" is coupled *directly* to the latex beads in Hughes & Morgan. Regarding claim 14, while the claim further limits the linker recited in claim 13 this claim reads on Hughes & Morgan because the claim still recites the moiety is directly linked to the binding partner. Claim 15 recites, "the moiety is coupled to the surface of the binding partner via *a covalent or non-covalent linkage*". While Hughes & Morgan is silent concerning the chemical nature of the binding between the "rabbit anti-goat IgG" and the "latex beads", it must be either covalent or non-covalent. Hence, this claim reads on Hughes & Morgan. Claim 16 recites, "the linkage between the moiety and the surface of the binding partner is effected via *a specific or non-specific binding*". While Hughes is silent concerning the specificity of the linkage, it must be either specific or non-specific. Hence, the claim 16 reads on Hughes & Morgan. Claims 19 and 49 recite, the physical force is selected from the group consisting of a dielectrophoresis,..". This claim is clearly anticipated by Hughes & Morgan since the entire article is concerned with dielectrophoresis. Claim 20 reads on Hughes & Morgan since the dielectrophoretic force is effected via electric fields produced by electrodes (see FIG. 2 of Hughes & Morgan). Claims 21 and 22 further limit the magnetic force recited in the Markush group of claim 19. Claims 23 and 24 further limit the acoustic force recited in the Markush group of claim 19. Claim 25 further limits the electrostatic force recited in the Markush group of claim 19. Claim 26 further limits the

mechanical force recited in the Markush group of claim 19. Claim 27 further limits the optical radiation force recited in the Markush of claim 19. All of these claims reads on Hughes & Morgan because they also recite a "dielectrophoretic force". Regarding claim 28, the glass chip recited therein reads on the "glass microscope slides" of Hughes & Morgan. Specifically. Hughes & Morgan teaches [page 3443, left hand column], "Electrodes were manufactured on a glass microscope slide...". Regarding claim 29, the energy source recited therein reads on the "Hewlett-Packard signal generator" of Hughes & Morgan. Claim 31 recites, "wherein the structure that is built-in the chip comprises a single unit...". This single unit reads on the electrode array of Hughes & Morgan. Claim 32 recites, the manipulation is selected from the group consisting of...separation..". This reads on the "DEP separation of sphere types" of Hughes & Morgan. Claim 42 reads on Hughes & Morgan is "rabbit anti-goat IgG" is clearly not directly manipulatable by a magnetic force. Claim 46 recites "*substantially* coupled" and claim 27 "*completely* coupled". "Substantially" and "completely" are relative terms. Since these terms are not defined in the claim and the specification does not provide a standard for ascertaining the requisite degree these claim read on Hughes & Morgan. Claims 48 and 49 read on Hughes & Morgan because the physical force of Hughes & Morgan is dielectrophoresis.

Claims 1, 2, 5, 7, 13, 16, 19, 27, 29, 31, 32, 35, 48, and 49 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Ulmer.

These claims read on the process of DNA manipulation of Ulmer. Specifically, Ulmer teaches [col. 22, lines 53-69]: "For example, in a preferred embodiment, a strand of DNA 66 is

immobilized by linkage to the microsphere 68 (claim 8) which is manipulated by a single-beam gradient optical trap 69 (the lasers tweezer recited in claim 26 read on the optical trap of Ulmer) shown in FIG. 8 ... Numerous methods exist in the art for attaching the DNA to the microscopic bead. Covalent chemical attachment the DNA to a microscopic bead can be accomplished by using standard coupling agents such as water-soluble carbodiimide, to link the 5'-phosphate on the DNA to amine-coated microspheres through a phosphoamidate bond. (claims 13 & 15) Another alternative is to first couple specific oligonucleotide linkers to the bead using similar chemistry, and then use DNA ligase to link the DNA to the linker on the bead. Oligonucleotide linkers can be employed to specifically hybridize to unique sequences at the end of the DNA fragment (claims 16 & 35), such as the overlapping end from a restriction enzyme site or the "sticky ends" of bacteriophage lambda based cloning vectors, but blunt-end ligations can also be used beneficially. Homopolymer linkers may also find utility in certain applications. By employing oligo-dT coupled to the bead, it will be possible to hybridize to the poly-A tail found in mRNA(claim 36).

While the term "chip" is not recited it is clear the system of Ulmer is a "chip" type device. This is evidenced by teachings in Ulmer such as , [col. 16, lines 27-30] "In a particular embodiment, the features of the micromachined body of the cleaving station are fashioned by a combination of lithographic techniques and selective etching." and [col. 16, lines 48-56] "Transport station 70 comprises a first microchannel 72 which is an extension of channel 62, a second surrounding microchannel 75, a nozzle 80 and a common exit microchannel 76."

Claims 1, 2, 5, 7, 8, 12, 17, 18, 33 and 34 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Briscoe et al.

Briscoe et al. discloses a "chip" for performing a variety of processes. Specifically, Briscoe et al. teaches [Abstract]: "A multilayered *microfluidic* DNA analysis system includes a cell lysis chamber, a DNA separation chamber, a DNA amplification chamber, and a DNA detection chamber.". The process recited in claim 34 reads on the process of Briscoe et al described in column 3, line 54 to column 4, line 26. Specifically Briscoe et al. teaches, "After cell lysis, fluid flow control system 30 allows the fluid containing the cell contents to pass *DNA* separation chamber 16. In chamber 16, the *DNA* from the cells is separated from the other cell contents. Preferably, the *DNA* separation is accomplished by *manipulating paramagnetic micro-beads*. Paramagnetic beads can be manipulated using magnetic fields, as the beads preferentially collect in the areas of high magnetic field strength. Thus, the paramagnetic beads can be entrained in chamber 16 by the application of a magnetic field. However, when the magnetic field is turned off, the beads are able to move through the fluid in chamber 16. The preferred paramagnetic beads have typical diameters in the range of 2.8 to 5 microns and preferentially adsorb duplex DNA under high salt (e.g. 3 to 4 molar Na^+) conditions...The paramagnetic beads are used to separate the DNA from the unwanted cell contents in the following way. First, fluid containing the paramagnetic beads is introduced into the chamber 16, such as through buffer injection port 18. The amount of paramagnetic beads to be added will depend on the amount of DNA that is anticipated will be recovered from the sample and on the rated DNA loading capacity for the

particular beads used. The beads are allowed to mix with the cell contents in chamber 16 for a few minutes. A magnetic field is then applied to chamber 16 to immobilize the paramagnetic beads,. With the beads immobilized, the buffer solution, typically about 3 to 4 molar Na^+, that is introduced through buffer injection port 18. In this flow, the buffer and unwanted cell contents are flushed out of chamber 16 through waste outlet port 20. Moreover, during this high salt wash step, the paramagnetic beads are entrained in chamber 16 by the magnetic field.". The "step of decoupling" recited in claim 33 reads on the elution step of Briscoe et al. which follows the process described above. Specifically, Briscoe et al. teaches [column 4, lines 27-34]: "After the high salt wash step, a low salt buffer, typically about 10 millimolar Na^+, is introduced into chamber 16 through buffer injection port 18. Under these low salt condition, the DNA elutes from the paramagnetic beads. With the paramagnetic beads entrained in chamber 16 by the use of the magnetic field, fluid flow control system 32 allows the low salt buffer containing the eluted DNA to pass to amplification chamber 22.".

Claims 1-10, 12- 21, 28, 32, 39, 48, and 49 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Parton et al.

Regarding claim 1, "the coupling "step recited therein reads formation of a complex of Parton et al. Specifically, Parton et al. teaches [col. 2, lines 50,-55]: "The nature of the treatment used to convert the original particle into an altered particle can vary widely according to the nature of the particle. The treatment may involve forming a complex between the particle and the ligand". The "moiety" of claim 1 corresponds to the "particle" of Parton et al. The "binding

partner' of claim 1 corresponds to the "ligand" of Parton et al. The manipulating step of claim 1 reads on the "migration" step of Patron et al. Specifically, Patron et al. teaches [ABSTRACT]: "Particles are subjected to traveling wave field migration (TWFM) to migrate the particles over an array of microelectrodes. Altered particles are produced by treating original particles in such a way as to alter their TWFM characteristics and the altered TWFM characteristics are employed for analysis and /or separation of the altered particles." Although the term "chip format" is not explicitly recited in Parton et al. the apparatus is clearly a "lab on a chip" device. Specifically. Parton et al. teaches [col. 6, lines 25-37]: "In FIG. 1, the array of electrodes is constituted by two parallel rows of electrodes, each electrode being rectangular and elongate transverse to the direction of extension of the rows. The two rows are separated by a gap of constant width and the separations between each pair of electrodes in each row is the same. The electrodes are thin metal film electrodes on an insulating substrate, suitably gold electrodes printed on a glass slide. The separation between the rows is 30 μm and the pitch between groups of four electrodes in each row is 80 μm. The "structure that is built-in said chip" corresponds to the "electrodes" of Parton et al. The "structure that is external to the chip" corresponds to the "field generator 108" of Parton et al. Regarding claims 2, 3, 5, and 7 Parton et al. teaches [col. 3, lines 38-49]: "The particle may be of a size visible using a light microscope (a microscopic particle) or may be smaller (a sub-microscopic particle) ... Examples of the former type of particles include mammalian cell, plant cells, yeast cells, plastic microbeads, chromosomes undergoing meiosis and mitosis and oocytes, e.g. of Cryptosporidium. Examples of the second type would include

bacterial cells, viruses, DNA or RNA molecules, proteins, other biomolecules, and chromosomes". While claim 4 further limits the cellular organelle recited in the Markush group of claim, claim 4 reads on Parton et al. because claim 4 recites a "cell", "virus", etc. While claim 6 further limits the "inorganic molecule" recited in the Markush group of claim 5, claim 6 reads on Parton et al. because claim 4 recites an organic molecule. Regarding claims 8, 12, and 13, Parton et al. teaches {ABSTRACT]: "They [particles] may be altered by binding to a ligand such as a metal micro particle via a selective linking moiety...". Claims 9 and 10, further limit the "cell" and "cellular organelle", respectively recited in the Markush group of claim 8. However, these claims read on Parton et al because they recite a "microparticle". Regarding claim 14, while Parton et al. does not explicitly recite that the linker is cleavable, this claim reads on the linking moieties of Parton et al. since any linking moiety is inherently "cleavable". Claim 15 recites, "wherein the moiety is coupled to the surface of the binding partner via *a covalent or non-covalent linkage*". This claim reads on Parton et al. since all linkages read on the above recitation. Claim 16 recites, "wherein the linkage between the moiety and the surface of the binding partner via *specific or a non-specific binding*". This claim reads on Parton et al. since all "bindings" read on the above recitation. Regarding claims 17 and 18, the limitations recited therein are considered to be inherent, even if the processes of Patron et al. do not include cleaving the linkage, since the claims recite the linkages be capable of cleavage. Claims 19, 20, 29, 49, and 49 read on Parton et al. because migration the result of traveling-wave dielectrophoresis. Although Parton et al. teaches [ABSTRACT]: "Particles are subjected to traveling wave field migration (TWFM) to migrate the

particles over an array of microelectrodes.", Parton et al. also teaches [col. 2, lines 9-11]: "We according prefer to refer to the phenomenon called previously "traveling wave dielectrophoresis" by the name "traveling wave field migration (TWFM).". Claim 32 reads on Parton et al. because discloses separation which is recited in the Markush group of claim 32. Regarding claim 39, the limitation concerning the complex recited therein reads on the complex illustrated in FIG. 8 of Parton et al. The complex illustrated in FIG. 8 consists of an antigen 16 attached to a micro particle 18 which has been modified with an antibody 14. The protein recited in this claim reads on the antigen since an antigen is defined [Webster's New World Dictionary, 3th ed.] as "a protein, toxin, or other substance of high molecular weigh, to which the body reacts by producing antibodies".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes & Morgan or Ulmer or Briscoe et al. or Parton et al.

Kit claims 68 and 69 merely recite the elements necessary for performing the process recited in claim 1. In other words there are no specific details of a kit. It would been obvious to

one of ordinary at the time of the invention to "package" any of the above references together with the elements necessary to perform the processes described therein because this would make performing these processes more convenient, i.e. eliminate purchasing the elements separately. In other words a package of the elements to perform a known process is an article of commerce not an invention.

Allowable Subject Matter

Claims 37, 38, and 50-52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (703) 308-1797. The examiner can normally be reached on Monday to Wednesday from 8:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

John S. Starsiak Jr.
24 September 2003